

REMARKS

Applicants respectfully request the Examiner to reconsider the present application in view of the foregoing amendments to the specification and claims and the following remarks.

Status of the Claims

In the present Amendment, claims 1 and 19 have been amended. Also, claims 2-14, 16, 20 and 23 have been canceled, wherein claims 17, 18 and 21 were previously canceled, without prejudice or disclaimer of the subject matter contained therein. Also, claims 24-25 have been added. Thus, claims 1, 15, 19, 24 and 25 are pending in the present application.

No new matter has been added by way of these amendments because each amendment is supported by the present specification. Applicants note, for instance, page 1, lines 1-2 and page 2, lines 17-20 of the present specification. Applicants also note, e.g., page 7, lines 16-17.

No new matter has been added with claims 24-25, which have support in claim 19.

The title of the specification has been amended. No new matter has been added.

Based upon the above considerations, entry of the present amendment is respectfully requested.

In view of the following remarks, Applicants respectfully request that the Examiner withdraw all rejections and allow the currently pending claims.

Objection to Specification

The Examiner has objected to the specification as the title not being sufficiently descriptive. Applicants note the changes to the title as shown herein. Thus, withdrawal of this

objection is respectfully requested.

Issues under 35 U.S.C. §102(b)

Claims 1 and 19 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,151,272 (hereinafter “Engstrom ‘272”).

Also, claims 1, 15 and 19 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,306,433 (“Andersson ‘433”).

Applicants respectfully traverse and request reconsideration.

The Examiner asserts that Engstrom ‘272 discloses compositions comprising a galactolipid bilayer and water (in a ratio of 5-50% by weight of water) together with a bioactive material that may be a protein (e.g., insulin). Furthermore, the Examiner explains that the Engstrom ‘272 compositions are (supposedly) suitable for controlled release.

The standard for determining novelty has been articulated by the Federal Courts, and is recited in the M.P.E.P. § 2131. For instance, the Federal Circuit has held that “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

In this regard, Applicant respectfully refer the Examiner to claims 1 and 19 as shown herein. The present invention is directed to colloidal protein-lipid complexes, and Engstrom ‘272 fails to disclose the colloidal feature. Applicants also note the specification at page 7, lines 16-17, which explains how colloidal systems are thermodynamically stable. In contrast, the compositions of Engstrom ‘272 specifically encompass liquid crystal systems. Colloids and

liquid crystals are discrete, mutually exclusive systems and, therefore, the subject matter of the present invention is patentably distinct from that of Engstrom '272.

Regarding the second rejection in view of Andresson '433, this reference also fails to disclose all instantly claimed features. In the Office Action, the Examiner asserts that Andersson '433 discloses a composition of bilayer-forming lipid (including galactolipid) and a bioactive protein wherein the ratio of peptide to lipid is 1:4. Moreover, since the peptide-lipid complexes of Andersson '433 are stated to be within 7 to 25 nm, they are also alleged to meet the limitations of claim 19 (which recites that the mean particle size to 100 nm or less). Finally the Examiner asserts that although the compositions of Andersson '433 are not stated to be colloidal, they would be inherently colloidal due to the peptide-lipid ratios and mean particle sizes disclosed. Applicants respectfully disagree, wherein the conclusion of inherency is improper.

First, U.S. case law states that inherency requires the missing element to be a *necessary* aspect of the invention. As recited by the M.P.E.P. § 2112 (IV) “[t]he fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art) (emphasis added in M.P.E.P.). As also cited in this part of the M.P.E.P., the Federal Circuit reaffirmed this position in the *In re Robertson* decision, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999), explaining that “[i]nherency...may not be established by probabilities or possibilities.”

Second, Applicants note the disclosure in Andersson '433 wherein the its lipid-protein mixtures of 7-25 nm particle size are not colloidal:

. . . This method results in a high yield from about 90 to 100% of [discolloidal] lipid particles comprised of phospholipids and protein with a particle size ranging from 7 to about 25 nm. The . . .

(See column 13, lines 44-47). Thus, there is no inherent disclosure of the present invention and Andersson '433 even specifically discloses the opposite.

Further, Applicants respectfully traverse this rejection on a technical level. If, for example, water and oil are mixed and they are immiscible, two separate layers are formed rather than a dispersed mixture. Moreover, the layers would not be expected to spontaneously form a colloid simply because a bioactive protein (e.g., insulin) was added. In fact, considerable downstream processing would have to be employed to form a stable colloidal system from such constituents. Therefore, the colloidal property of the cited Andersson '433 reference, if it is even capable of forming or may form a colloidal suspension at all, would not be an inherent feature of the present invention. *Robertson; supra*.

One suitable process for the formation of the presently claimed colloidal suspensions is outlined in the present application on page 7, line 26 to page 8, line 10 of the specification as filed. However, it is notable that this novel process utilizes considerably less extreme conditions than those of the common general knowledge (as discussed at page 8, lines 24-30 of the application). Spontaneous colloid formation is not an intrinsic feature of the compositions of Andersson '433 or even of the present invention.

Based upon the evidence and arguments presented herein, Applicants respectfully submit that each of Engstrom '272 and Andersson '433 fails to disclose all claimed features. Thus, Applicants respectfully request reconsideration and withdrawal of both rejections.

Conclusion

In view of the above amendment, applicant believes the pending application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Eugene T . Perez, Reg. No. 48,501, at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

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Respectfully submitted,

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